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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/544,154

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Francis X. Smith

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EXAMINER

BASQUILL, SEAN M

ART UNIT

PAPER NUMBER

1612

MAIL DATE

DELIVERY MODE

12/03/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/544,154	Applicant(s) SMITH, FRANCIS X.	
	Examiner Sean Basquill	Art Unit 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 September 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Previous Rejections

1. Applicants' arguments, filed 16 September 2009 have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Claims 1-3 and 5-20 stand rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,817,277 ("Mowrey-McKee"), in view of U.S. Patent 5,741,817 ("Chowhan") for the reasons put forth in the office action of 9 June 2009.

Applicants arguments have been fully considered and are deemed unpersuasive. Applicants sole avenue of rebutting the examiner's prima facie case of obviousness lies in the argument that because Chowhan indicates that "some scientific studies have indicated that EDTA may damage corneal cells," this amounts to a teaching away from the use of amino acids such as histidine in ophthalmic compositions. This is not found persuasive for three reasons: the so-called "warning" against the use of EDTA is unconvincing, EDTA is well-known and generally recognized as safe, effective and desirable in ophthalmic compositions, and taken as a whole the state of the art fails to teach away from the combination of EDTA and histidine.

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First, Chowhan's warning concerning the potential hazards of EDTA use in ophthalmic compositions is simply that – a warning of potential hazards and not an absolute proscription on its use. Second, in addition to alluding to some potential hazard, Chowhan affirmatively indicates that EDTA has “been widely used for many years in ophthalmic products, particularly products for treating contact lenses.” (C.1, L.20-22). The uses to which EDTA has been put in such compositions varies widely, but in particular it is known “for its supplemental antimicrobial activity and as a chelating agent...[which] enhances the antimicrobial efficiency of chemical preservatives contained in such compositions.” (C.1, L.24-28). In sum, Chowhan teaches both the use of amino acids such as histidine as well as EDTA as components of ophthalmic compositions which are each individually known to enhance the antimicrobial efficiency of chemical preservatives used therein. Many compounds generally recognized as safe and effective come with what amounts to little more than either boilerplate warnings designed to satisfy legal counsel’s desire to avoid product liability suits, or mere puffery aimed at improving the appearance of one’s own product; the examiner considers the warning contained in Chowhan, such as it is, as falling within either or both of the aforementioned categories.

Thirdly, given the above teachings from within Chowhan, which the examiner asserts represents the state of the art at the time of the filing of the instant application, applicants have failed to convincingly demonstrate that the art teaches away from the combination of EDTA and amino acids such as histidine in ophthalmic compositions. To properly argue that prior art is either incapable of being combined or teaches away from the combination suggested by the examiner, applicants must either indicate how the claimed combination would change the principle of operation of the primary reference or render it inoperable for its intended purpose,

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MPEP § 2145(III), or “criticize, discredit, or otherwise discourage the solution claimed.” MPEP § 2145(X)(D), *citing In re Fulton*, 391 F.3d 1195, 1201 (Fed. Cir. 2004). Here, applicants have offered no evidence to establish either that the combination suggested by the examiner would render the primary reference inoperable for its intended purpose or presented evidence to establish that the combination claimed has been criticized, discredited, or otherwise discouraged. *See* MPEP § 2145(I) (indicating attorney argument does not replace evidence where evidence is required). As described in greater detail above, the examiner asserts that the combination of EDTA and amino acids in ophthalmic compositions may actually be encouraged by the disclosure of Chowhan, notwithstanding the preferred embodiments which do not contain EDTA. *See* MPEP § 2123 (indicating that disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments). Where a prior art disclosure provides teachings that would suggest to the artisan possessing ordinary skill a rationale for combining two components individually taught in the art as useful for the same purpose, the combination is *prima facie* obvious. The idea for combining them flows logically from their having been individually taught in the prior art. MPEP § 2144.06. Here, Chowhan indicates that both EDTA and amino acids such as histidine are useful for increasing the efficacy of antimicrobial components of ophthalmic compositions. This not only suggests the suitability of each enhancer either alone or in combination, but would also reasonably suggest that a similar enhancement of antimicrobial effect may be achieved by using less of either individual enhancer in such a combination, when compared with the amounts needed to achieve the same enhancement effect using either enhancer alone.

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For at least the above reasons, applicants rebuttal arguments are deemed unpersuasive and, until sufficient evidence of secondary indicia of nonobviousness commensurate in scope with the invention as claimed is provided, the obviousness rejection stands.

3. Claims 1-20 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Mowrey-McKee as modified by Chowhan as applied to claims 1-3 and 5-20 above, and further in view of U.S. Patent 5,620,970 ("Han") for the reasons put forth in the office action of 9 June 200.

Applicants arguments have been fully considered and are deemed unpersuasive for the reasons put forth above concerning the rejection over Mowrey-McKee in view of Chowhan.

Double Patenting

4. Claims 1-14, 16, 18-20 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 2, 4, 7, 8, and 10-19 of copending Application No. 11/613,061.

This rejection is maintained since applicant has (effectively) not responded to the rejection in a substantive manner. See 37 CFR § 1.111(b) and MPEP § 714.02.

5. Claims 1-20 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5, 7-13 of copending Application No. 10/544,149 in view of U.S. Patent 5,741,817 ("Chowhan").

This rejection is maintained since applicant has (effectively) not responded to the rejection in a substantive manner. See 37 CFR § 1.111(b) and MPEP § 714.02.

6. Claims 1, 3-12 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5 and 8 of copending Application No. 11/613,050 in view of U.S. Patent 5,741,817 ("Chowhan").

This rejection is maintained since applicant has (effectively) not responded to the rejection in a substantive manner. See 37 CFR § 1.111(b) and MPEP § 714.02.

Conclusion

No Claims stand allowable.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean Basquill whose telephone number is (571) 270-5862. The examiner can normally be reached on Monday through Thursday, between 8AM and 6PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Sean Basquill
Art Unit 1612

/JEFFREY S. LUNDGREN/
Primary Examiner, Art Unit 1639